

REMARKS

All the claims submitted for examination in this application have been made subject to a restriction requirement. The outstanding Official Action alleges that there are four independent and distinct inventions embodied by the 43 claims originally submitted in this application.

The first of these inventions is denoted as Group I. Group I, which includes Claims 1 to 15, is drawn to compounds, classified in Classes 540, 544, 546 and 548, various subclasses.

The second invention, Group II, includes Claims 16 to 30, drawn to multiple uses and compositions, classified in Class 514, various subclasses.

The third invention is Group III, encompassing Claims 31-42, drawn to compositions and multiple uses containing any unknown additional active ingredient, classified in Class 514, various subclasses.

Finally, the fourth and last invention is embodied by Claim 43, drawn to intermediates, classified in Classes 540, 544, 546 and 548, various subclasses.

Applicants have considered this requirement for restriction and have elected, for prosecution on the merits in this application the invention denoted as Group I. This election is made with traverse.

The Official Action avers that the inventions of Groups I and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctiveness is proven for claims in this relationship if the intermediate product is useful in making other than the final product (MPEP §806.04(b) 3rd paragraph) and the species are patentably distinct (MPEP §806.04(h)). In the instant case, the Official Action avers that the intermediate

product is useful as a herbicide, an insecticide, a fungicide, a photographic antifogging agent and the like.

Applicants respectfully demur from the conclusion that the requirements of an intermediate-final product relationship is established. There is no evidence to support the conclusion reached that the intermediate compounds of Claim 43 find utility as herbicides, insecticides, fungicides, photographic antifogging agents and the like. That the intermediate compound of Claim 43 is submitted to be novel, it is not seen how this conclusion can be drawn. The conclusion reached in the Official Action is mere speculation devoid of any proof. The Official Action does not so much as provide any argument in support of the allegation that the generic compound of Claim 43 is useful in any of the applications mentioned in the Official Action.

The second basis for the present restriction requirement is that the claims that constitute the Group I and Group II inventions are related as a product and a process of use. Inventions of this kind can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP § 806.05(h)). The Official Action states that in the present case the product as claimed can be used in materially different processes as evidenced by applicants' own claims and specification. Applicants do not traverse this ground in support of distinctiveness between the claims of Groups I and II. That is, applicants concede that the inventions of Group I and Group II are distinct.

The third basis for imposition of the restriction requirement of record is directed to the distinction between the inventions of Groups I and III. The Official Action argues that the

claims of Group III are patentably distinct from the claims of Group I because they require an additional active ingredient. In support of this ground of rejection the Official Action points to the invention of Group II which provides evidence that an additional active ingredient is not necessary for patentability of the claimed compounds.

Applicants respectfully traverse this ground for restriction. Proofs of distinctiveness, to support a restriction requirement, are set forth in the MPEP, as indicated by the above recited application of sections of the MPEP. Applicants submit that the absence of the application of a section of the MPEP in support of the distinctiveness between the claims of Groups I and III establishes the absence of any ground that supports distinctiveness. In the absence of a basis for distinctiveness sanctioned by the Manual of Examining Procedure, applicants submit that distinctiveness between the claims of Group I and II is not established.

In further accordance with the requirement for restriction applicants have elected, as a single use, the treatment of Alzheimer's Disease. This election is likewise made with traverse.

The above remarks, which establish that the Official Action assertion of distinctiveness between the four sets of claims is not met, is buttressed by a second basis for removal of the provisional restriction requirement of record. That is, the statute, 35 U.S.C. §112, in its first sentence, states:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. (Emphasis added.)

Pursuant to this statutory dictate, the implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions

which are both independent and distinct. 37 C.F.R. §§1.141 - 1.142. Without both independence and distinctiveness, a restriction requirement is not authorized.

In the present application the four sets of claims, which the Official Action has grouped separately, are not independent of each other so as to justify a restriction requirement. The claims of Group I to IV, Claims 1-43, are drawn to compounds, their uses, intermediate compounds employed in their synthesis and composition which include those compounds. None of these claims cannot be considered "independent" of each other. Rather, these sets of claims are interrelated and interdependent.

The interdependence of the four allegedly distinct and independent sets of claims, set forth in the Official Action, is confirmed --indeed, it is mandated-- by virtue of the fact that the descriptive requirements of 35 U.S.C. §112 compel disclosure of all aspects of the four allegedly distinct and independent inventions of the present application. An application claiming a compound must, of necessity, also describe the intermediate compounds of Claim 43, which constitute the reactants in their synthesis. Similarly, the utility of these claimed compounds, as set forth in the methods of Claims 19-30, 34, 36, 40 and 43, and the compositions containing these compounds, as set forth in Claims 16-18 and 31, 33, 35, 37, 39 and 41, must be described in the invention of the compounds of Claims 1 to 15. Failure to include a description of the subject matter of these claims would be defective under 35 U.S.C. §112, first paragraph.

The above discussion establishes that all the claims of the present application are interdependent rather than independent. Therefore, the instant restriction requirement is defective insofar as none of the four sets of claims have been established to be independent.

As such, even the restriction requirement in regard to the claims of Group II should be rescinded.

The outstanding Official Action, imposing the above-discussed provisional restriction requirement, also relies on the recital of the applicable sections of the Manual of Patent Examining Procedure (MPEP). Reference to the MPEP does not establish compliance with the narrow statutory authorization for a restriction requirements. The MPEP simply states the policy of the Patent and Trademark Office without the force of law. As such, the MPEP is not authority for expanding or altering a statutory grant of authority. This point is made by no lesser authority than the Commissioner of Patents and Trademarks who has stated:

The PTO can proscribe requirements in the MPEP provided these requirements are not inconsistent with the statute, the rules or the case law of the PTO's reviewing court. In re Fressola, 22 USPQ2d 1832 (Comm'r. PTO 1992).

Of course, failure to meet the distinctiveness requirements of the MPEP, as in the present application, establishes that distinctiveness has not been established.

It is emphasized that the restriction requirement of record is not mandatory and is indeed contrary to the public interest. Courts have recognized that it is in the public interest to permit an applicant to claim all aspects of an invention in a single application, as applicants have done herein. The CCPA has observed:

We believe that the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe, in a manner required by 35 U.S.C. §112, all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. In re Kuehl, 456 F.2d 658, 666, 117 USPQ 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed description supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application directed to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase in official fees and the resultant potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose of promoting and encouraging the progress of science and the useful arts.

It is vital that restriction requirements issue only with the proper statutory authorization because patents issuing on divisional applications, which are filed to prosecute claims that are held to be distinct and independent, can be vulnerable to legal challenge predicated upon the allegation of double patenting.

The third sentence of 35 U.S.C. §121, which states that a patent issuing on a patent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same invention double patenting. Studiengellschaft Kohle mvP v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 USPQ 837, 840 (Fed. Cir. 1986).

The same Court in Gerber Garment Technologies Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 USPQ 2d 1436 (Fed. Cir. 1990) held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting and, in fact, the invalidation, on double patenting grounds, of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a Terminal

Disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on a divisional application.

All of these considerations indicate that the imposition of a restriction requirement without adequate authority can lead to a situation in which an applicant's legitimate patent rights are exposed to uncertainty and even distinguishment. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, applicants respectfully urge the removal of the instant provisional restriction requirement wherein all aspects of the single invention defined by all the claims of this application, Claims 1 to 43, are examined on the merits therein.

Applicants, pursuant to the species election imposed in the outstanding Official Action, have elected the species N-[5-(cis-3-acetylamino-cyclobutyl)-1H-pyrazol-3-yl]-naphthalen-1-yl-acetamide. It is noted that it is unclear whether a species election has been imposed in the outstanding Official Action. All that is stated is that in the event of an election of Group I, which is the case, the examination of this application will be limited to the elected compound. Thus, applicants assume that in the event that a generic class is not found patentable the present species election will limit the invention to the species elected.

Applicants traverse what they assume is a species election. Applicant respectfully submit that the species election of record is unduly limiting.

Applicants aver that the number of species within the contemplation of the claims of the present application are not so numerous as to impose the draconian requirement that the claims be limited to a single species. Rather, the generic class of compounds within the contemplation of Claims 1 to 15, in the event that the restriction requirement is made final, should not be limited to the elected species.

The above remarks prompt the conclusion that all the claims submitted for examination, Claims 1 to 43, should be examined on the merits in this application. Prompt examination on the merits followed by Notice of Allowance of all the claims of this application, Claims 1-43, is therefore respectfully solicited.

Respectfully submitted,



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